Citation:

Howe PR, Cobiac L, Smith RM. Lack of effect of short-term changes in sodium intake on blood pressure in adolescent schoolchildren. *J Hypertens.* 1991 Feb; 9 (2): 181-186.

PubMed ID: 1849536

Study Design:

Randomized controlled trial with crossover

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

- To examine the effects of short-term (four weeks) dietary sodium restriction on blood pressure (BP) in adolescent children
- To test whether BP response is dependent on initial level of BP in this group.

Inclusion Criteria:

- Children who attended school in Adelaide, Australia
- Aged 11 to 15 years at entry into the study
- Average values of diastolic blood pressure (DBP) were used to select children representing different levels of the BP distribution
- Equal numbers of males and females from the top, middle and bottom deciles of the distribution were invited to participate.

Exclusion Criteria:

Children who did not meet the inclusion criteria were excluded. No other exclusion criteria were reported.

Description of Study Protocol:

Recruitment

Children aged 11 to 15 years were recruited from two independent schools in Adelaide, Australia.

Study Design

Randomized controlled trial with crossover.

Intervention

A randomized crossover dietary intervention with four weeks each of either a high- or low-sodium (Na) diet.

- Participants attended group meeting with their parents during which the diets were explained in detail
- Targets were: <75mmol low Na period
- More than 150mmol per day high Na period
- Dietary counseling was continued at each weekly visit
- Weekly diet histories were taken
- Diet instruction reinforced
- Feedback of results of urinary Na analysis were used to help attain dietary Na targets
- Low-sodium bread and salt sachets were distributed to assist in attaining dietary Na targets
- Three-day diet diaries were taken at the end of each period.

Statistical Analysis

- Effects of dietary crossover on systolic blood pressure (SBP) and DBP and urinary sodium (UNa) per day were assessed by comparing
    - Final measurement taken at the end of each diet period
    - Average of all measurement taken during each diet period
- Effect on nutrient intakes was assessed by comparing the diet diaries from each diet period
- Within child differences were determined using a paired T-test
- Separate analyses were made when the group was divided by sex, diet diary completion, and for each of the three BP deciles
- Correlation between changes in BP and changes in Na excretion were examined by linear regression
- Ambient temperature was included in the model to control for that possible effect on BP and was assessed with analysis of covariance (ANCOVA).

Data Collection Summary:

Timing of Measurements

- After a pre-intervention visit, the children were randomized to adopt a high- or low-Na diet for four weeks, and then changed to the alternate diet for a further four weeks
- Weekly visits were held to monitor diet adherence and to measure BP.

Dependent Variables

SBP and DBP in children

- Blood pressure was measured weekly with an automated monitor
- Cuff sizes were selected in accordance with the manufacturer’s guidelines
- The measurement was taken while the subjects were supine and two readings were taken and averaged after the subjects had 15-minute rest
- Ambient temperature was recorded.

Independent Variables

Urinary sodium per day

- On the morning of each BP measurement a first void of urine was collected and the Na concentration was estimated by the equation: Na per day=(Na: creatinine) x (creatinine per day) x 1.64
- Sodium and potassium (K) contents in the urine were analyzed by flame photometry.

Control Variables

- Sex
- BP deciles
- Diet diary completion.

Description of Actual Data Sample:

- *Initial N:*
  - 692 children aged 11-15 years were initially screened
  - After applying the selection criteria 103 children accepted the invitation to join the study
- *Attrition (final N):*
  - The final analysis was done on 100 subjects. There was no discussion about why three subjects were not included
  - 52 were boys and 48 girls
- *Age:* Mean (SE) 13.3 (0.1) years
- *Ethnicity:* Not described
- *Other relevant demographics:* Not applicable
- *Anthropometric characteristics at entry into study:* Mean (SE)
  - SBP (mmHg) 115.0 (1)
  - DBP (mmHg) 60.1 (0.6)
  - Height (cm) 160.0 (1)
  - Body weight (kg) 51.0 (1)
- *Location:* Adelaide, Australia.

Summary of Results:

Variables

- Change in SBP and DBP
- UNa.

Dependent Variable 1

Change in BP: SBP and DBP

- Comparing the mean BP values for all subjects at the end of each diet period or the average from the weekly readings there were no significant (NS) differences in SBP (Table 1 below) or DBP between diets
- ANCOVA revealed than increase in ambient temperature of one degree centigrade lowered supine SBP and DBP by 0.15mmHg and 035 mmHg respectively
- Blood pressure measurements were adjusted accordingly; however the adjustment had little influence on the data
- Despite a significant change in DBP in the lowest decile, there was NS correlation within individuals between initial BP and change of DBP and SBP

- Correlation between changes in Na and BP failed to reach significance.

Table 1. Changes in Blood Pressure Between High and Low Sodium Diets in Children

Difference Between Final Measurement on High- and Low-sodium Diets (mmHg)				
	Unadjusted		Temperature-adjusted	
	SBP	DBP	SBP	DBP
All children	0.97±0.68	0.56±0.71	0.97±0.68	0.78±0.68
Those in highest BP decile	-0.41±1.15	-1.39±1.34	-0.52±1.14	-1.65±1.22
Those in lowest BP decile	1.13±1.07	2.05±1.19	1.03±1.02	2.52±1.10*

Mean ± SEM; *P<0.05; paired T-test.

Independent Variable Sodium Excretion and Intakes

- Overall difference in UNa was 81mmol per day between the final weeks of the low- and high-Na periods
- Children who completed the diet diaries (it was assumed that they were more adherent to the diet) difference in UNa was 104mmol per day
- Diet diaries were used to measure daily intakes of Na, K, calcium, macronutrients, fiber and energy
    - Na intake was 61% lower during the low Na period, however K was unaffected
    - There was a significant increase (13%) in fiber, but no changes in macronutrient or energy intake
    - Body weight was unaffected by the interventions.

Author Conclusion:

The authors concluded that there was NS lowering effect of moderate dietary sodium restriction on SBP or DBP in adolescents, even in those in the highest blood pressure tertile, who may be predisposed to hypertension.

Reviewer Comments:

Strengths

- *Even though the authors stated that subject dietary compliance was variable, the subjects got adequate support to make the required dietary changes*
- *Parents and children received regular dietary counseling and the results of UNa analysis were reported back as an aid to adherence*
- *High follow-up rate.*

Limitations

- *Along with sodium, potassium may be important in BP regulation. The authors stated that dietary potassium did not change, but they did not discuss urinary potassium or its relationship to the BP deciles or changes in SBP or DBP*
- *Limitations, which might lead to a spurious null result, include variable adherence (the trial was not a controlled feeding study) and the small number of BP measurements (only one set*

per week), thereby reducing statistical power.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes
Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	No
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes

3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	No
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	???
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	???
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes

6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	???
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	N/A
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	No
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes

8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	Yes
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	N/A
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	N/A
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes